

**Notice of Allowability**

Application No.

10/009,341

Applicant(s)

MARECHAL ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 27 October 2005.
2. ☒ The allowed claim(s) is/are 6-11, 13-16 and 18-23.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The Drawings filed 06/19/02 are accepted by the Examiner.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
- ☒ Examiner's Amendment/Comment
- ☐ Examiner's Statement of Reasons for Allowance
- ☐ Other \_\_\_\_\_

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Notice of Appeal, the Amendment and Response under 37 C.F.R. 1.116, Applicant's Arguments/Remarks and the request for extension of time (2 months-granted), all filed 10/27/05 is acknowledged.

Claims 6-11, 13-16 and 18-23 are pending in this action. Claims 6-9 and 11 have been amended. Claims 1-5, 12 and 17 have previously been cancelled. Claims 6-11, 13-16 and 18-23 are allowed.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Matthew E. Mulkeen on December 16, 2005.

The application has been amended as follows:

#### In the Claims:

In claim 6, line 10, before the word 'lubricant', the term "**conventional**" has been **deleted**.

In the Specification, on page 6, line 6, the phrase "Brief Description of the Drawings" has been added.

Abstract: A new Abstract contained in one paragraph has been provided.

***Allowable Subject Matter***

Claims 6-11, 13-16 and 18-23 are allowed.

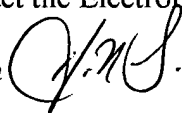
**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh



Patent Examiner

Art Unit 1615

December 16, 2005

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

### **Abstract**

The present invention concerns a novel sustained-release oral formulation of morphine sulphate in the form of microgranules. Each microgranule comprises a neutral support grain coated with an active layer and with a sustained-release layer, characterized in that the sustained-release layer contains a copolymer of methacrylic acid and of methyl methacrylate ester, the relative proportion of the free carboxyl groups and of the ester groups of which is equal to 0.5 approximately, and a silica exhibiting a hydrophobic character. The present invention also concerns a process for preparing these microgranules which is carried out entirely in aqueous medium by emplacing on neutral support grains.